

What is claimed is:

1. A pharmaceutical composition of desloratadine comprising of a mixture of crystalline form desloratadine I and II in a weight to weight ratio of about 25% to about 75% of either form to the other and a pharmaceutically acceptable excipient.
- 5 2. The pharmaceutical composition of claim 1, wherein the ratio is approximately 50%.
3. The pharmaceutical composition of claim 1, wherein the ratio is of about 55 to about 65% Form I to about 35 to about 45% of Form II.
4. The pharmaceutical composition of claim 1, wherein the mixture used for  
10 composition has a melting temperature of about 157°C to about 158°C as measured by DSC.
5. The pharmaceutical composition of claim 1, wherein the mixture used for composition undergoes less than about 1% by weight polymorphic change and chemical degradation after grinding for one minute.
- 15 6. The pharmaceutical composition of claim 1, wherein the mixture used for composition undergoes less than about 1% by weight chemical decomposition after storage at 100% relative humidity for one week.
7. The pharmaceutical composition of claim 1, wherein the mixture used for composition undergoes less than about 10% polymorphic change for each polymorph  
20 after storage for 2 months at 40°C at 75% RH.
8. The pharmaceutical composition of claim 7, wherein the mixture used for composition undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
9. The pharmaceutical composition of claim 8, wherein the mixture used for  
25 composition undergoes less than about 3% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
10. The pharmaceutical composition of claim 1, wherein the mixture used for composition undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.
- 30 11. The pharmaceutical composition of claim 10, wherein the mixture used for composition undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

12. The pharmaceutical composition of claim 11, wherein the mixture used for composition undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.
13. The pharmaceutical composition of claim 1, wherein the mixture used for  
5 formulation complies with the GMP requirements.
14. A method of preventing or treating allergenic reactions in a mammal comprising administering the pharmaceutical composition of claim 1 to the mammal in need thereof.
15. A pharmaceutical composition of desloratadine comprising of crystalline form desloratadine I and II in a weight to weight ratio of about 20% to about 40% of Form II  
10 and a pharmaceutically acceptable excipient.
16. The pharmaceutical composition of claim 15, wherein the Form II content of the mixture is about 24% to about 38%.
17. The pharmaceutical composition of claim 15, wherein the mixture used for composition has a melting temperature of about 157°C to about 158°C as measured by  
15 DSC.
18. The pharmaceutical composition of claim 15, wherein the composition undergoes less than about 1% by weight polymorphic change and chemical degradation after grinding for one minute.
19. The pharmaceutical composition of claim 15, wherein the composition undergoes  
20 less than about 1% by weight chemical decomposition after storage at 100% relative humidity for one week.
20. The pharmaceutical composition of claim 15, wherein the composition undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
- 25 21. The pharmaceutical composition of claim 20, wherein the composition undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
22. The pharmaceutical composition of claim 21, wherein the composition undergoes less than about 3% polymorphic change for each polymorph after storage for 2 months at  
30 40°C at 75% RH.
23. The pharmaceutical composition of claim 15, wherein the composition undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

24. The pharmaceutical composition of claim 23, wherein the composition undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.
25. The pharmaceutical composition of claim 24, wherein the composition undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.
26. The pharmaceutical composition of claim 15, wherein the mixture complies with the GMP requirements.
27. A method of preventing or treating allergenic reactions in a mammal comprising administering the pharmaceutical composition of claim 17 to the mammal in need thereof.
28. A stable mixture of crystalline form desloratadine I and II in a weight to weight ratio of about 25% to about 75% of either form to the other, wherein the mixture is stable in that it undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
29. A stable mixture of crystalline form desloratadine in a weight to weight ratio of from about 20-40% Form II to about 60-80% Form I, wherein the mixture is stable in that it undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
30. The stable mixture of claim 29, wherein the weight to weight ratio is from about 24-38% Form II to about 62-76% form I.
31. The stable mixture of any of claims 28 or 29, having a melting point in the range of 157-158%.
32. The stable mixture of claim 28 or 29, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
33. The stable mixture of claim 32, wherein the mixture undergoes less than about 3% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
34. The stable mixture of any of claims 28 or 29, wherein the mixture undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.
35. The stable mixture of claim 34, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

36. The stable mixture of claim 35, wherein the mixture undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.
37. A mixture of crystalline form desloratadine I and II in a weight to weight ratio of about 25% to about 75% of either form, prepared by a process comprising:
- i) combining desloratadine salt, toluene and a base to obtain a reaction mixture;
  - j) heating the mixture, whereby two phases are obtained;
  - k) separating the phases;
  - l) concentrating the separated organic phase;
  - 10 m) dissolving the obtained concentrate in a toluene-2-propanol mixture containing less than about 20% 2-propanol by volume;
  - n) cooling the solution to obtain a slurry;
  - o) combining the slurry with cold n-heptane; and
  - p) recovering mixture of desloratadine forms I and II.
- 15 38. The stable mixture of claim 37, wherein the process further comprises washing the product of step c with water.
39. The stable mixture of claim 37, wherein the process further comprises warming the product of step f to 45°C.
40. The stable mixture of claim 37, wherein the mixture undergoes less than about 20 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
41. The stable mixture of claim 40, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
42. The stable mixture of claim 41, wherein the mixture undergoes less than about 3% 25 polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
43. The stable mixture of claim 37, wherein the mixture undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.
44. The stable mixture of claim 43, wherein the mixture undergoes less than about 5% 30 polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

45. The stable mixture of claim 44, wherein the mixture undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.
46. The stable mixture of claim 37, wherein the mixture complies with the GMP requirements.
47. The stable mixture of claim 37, wherein the dissolution rate in vitro of the stable mixture, when measured by the U.S.P Paddle Method at 50-90 RPM in 900mL water is not less than 80% (by weight) of the mixture released after 30 minutes.
48. A pharmaceutical formulation comprising the stable mixture of claim 37.
49. A pharmaceutical composition of desloratadine prepared by a process comprising the steps of:
- a) preparing a mixture of crystalline form desloratadine I and II in a weight to weight ratio of about 20% to about 40% Form II to Form I; and
  - b) combining the mixture with a pharmaceutically acceptable excipient to obtain a pharmaceutical composition.
50. The pharmaceutical composition of claim 49, wherein the mixture used for composition has a melting temperature of about 157°C to about 158°C as measured by DSC.
51. The pharmaceutical composition of claim 49, wherein the mixture undergoes less than about 1% by weight polymorphic change and chemical degradation after grinding for one minute.
52. The pharmaceutical composition of claim 49, wherein the mixture undergoes less than about 1% by weight chemical decomposition after storage at 100% relative humidity for one week.
53. The pharmaceutical composition of claim 49, wherein the mixture undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
54. The pharmaceutical composition of claim 53, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.
55. The pharmaceutical composition of claim 54, wherein the mixture undergoes less than about 3% polymorphic change for each polymorph after storage for 2 months at 40°C at 75% RH.

56. The pharmaceutical composition of claim 49, wherein the mixture undergoes less than about 10% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

57. The pharmaceutical composition of claim 56, wherein the mixture undergoes less than about 5% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

58. The pharmaceutical composition of claim 57, wherein the mixture undergoes less than about 1% polymorphic change for each polymorph after storage for 2 months at room temperature at 60% RH.

59. The pharmaceutical composition of claim 49, wherein the mixture complies with the GMP requirements.

60. A method of preventing or treating allergenic reactions in a mammal comprising administering the pharmaceutical composition of claim 49 to the mammal in need thereof.

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